Pine Chemicals Association, Inc.

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June 3, 2002

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 22116

Attention: Chemical Right-to-Know Program

Re: Response to Comments and Amendments to Pine Chemicals Association, Inc. Test Plan for Tall Oil and Related Substances

Dear Ms. Whitman:

The Pine Chemicals Association, Inc. (PCA) HPV Task Force is pleased to submit its response to comments received on its May 2001 Test Plan for Tall Oil and Related Substances. We have carefully reviewed the comments submitted by the Environmental Protection Agency (EPA) in December 2001 and by the Environmental Defense and Physicians Committee for Responsible Medicine in November 2001. This document responds to those comments and amends our May 2001 Test Plan. We have organized the submission by subject matter in the same order as our Test Plan.

RESPONSE TO COMMENTS & AMENDMENTS TO TEST PLAN

Categorization of Substances / Selection of Test Material

PCA proposed to group seven substances in its Test Plan for Tall Oil and Related Substances. Under this Test Plan, PCA proposed to test tall oil (CAS # 8002-26-4) to represent the category based on its use as the raw material for most of the other category members and the fact that most of substances in the category are predominantly tall oil or its salts.

Although EPA agreed with the overall proposed category, the Agency suggested that PCA may want to consider whether tall oil pitch (CAS # 8016-81-7), pitch salt (CAS # 68140-16-9), and disproportionated tall oil (CAS # 68152-92-1) should also be tested. The Agency believes that the test results for tall oil may not be representative of these substances because their compositions may be significantly different. Environmental Defense (ED) also suggested testing tall

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oil pitch due to potential differences in composition. The Physicians Committee for Responsible Medicine (PCRM)[1], on the other hand, criticized PCA for not expanding the category to include six additional substances from its Test Plan for Tall Oil Fatty Acids (TOFA) and Related Substances and four additional substances being sponsored by a consortium of the Soap and Detergents Association (SDA).

After carefully considering these comments, PCA believes that its categories and representative test substance should remain as originally proposed; however, we will conduct an additional acute toxicity test (OECD 425, the up-down procedure) on tall oil pitch to address the Agency's concerns. Our rationale is discussed in detail below.

EPA recommended that PCA consider testing disproportionated tall oil. The Agency was concerned that the process of catalytic conversion of the conjugated double bonds during production of disproportionated tall oil might result in a significant change in the chemical composition of the fatty acids relative to the original distilled tall oil. However, as demonstrated in the table below, the chemical composition of disproportionated tall oil is very similar to distilled tall oil (the representative test substance).

Composition of Distilled Tall Oil and Disproportionated Tall Oil

Component	**Distilled Tall Oil (% composition)**	**Disproportionated Tall Oil (% composition)**
Palmitic	3	3
Stearic	2	2
Oleic/elaidic	28	43
Linoleic	28	9
Unknown Fatty Acids	8	6
Isopimaric	3	2
Abietic	10	1
Dehydroabietic	5	12
Unknown Resin Acids	11	16

[1] PCRM's comments were also submitted on behalf of People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute.

As shown, the substances are comprised of the same constituents at varying ratios. There is no reason to believe that these different ratios would affect potential toxicity. Thus, the toxicity of disproportionated tall oil should be similar to distilled tall oil. Accordingly, the test results on distilled tall oil should be representative of disproportionated tall oil.

Similarly, EPA and ED raised concerns that the results of toxicity testing on tall oil might not be representative of tall oil pitch and pitch salt. EPA reasoned that the substances must be substantially different in composition due to the lack of an adequate analytical method to fully characterize tall oil pitch. EPA stated, "This inability to fully characterize the tall oil pitch suggests that substantive changes may have occurred in the processing."

Pitch is an extremely complex material as its components are either formed during the high temperature (i.e., > 300°C) distillation of tall oil, another complex material, or are the high boiling components of the original tall oil. Consequently, the composition of pitch can only be expressed in a general way with the major components consisting of fatty acids and rosin acids, esters of fatty acids, dimerized acids, and rosin acids, as well as neutral materials. While available data suggest that the various known components have a very low order of toxicity, as suggested by EPA, PCA will undertake an acute toxicity test on tall oil pitch to assess this endpoint using OECD 425 (the "up-down" procedure) thus minimizing the number of animals used. It is anticipated that this proposed testing will demonstrate that tall oil pitch has similar toxicity (or lack thereof) to distilled tall oil, the representative test substance. In addition, since EPA's HPV Guidelines for grouping chemicals into a category endorse the use of the "family approach" of examining related acids and acid salts, the acute toxicity results for tall oil pitch should also demonstrate that tall oil pitch salt will have similar toxicity to distilled tall oil, the compound selected as representative of this category.

On a more general note, Environmental Defense recommended the development of microarray technology protocols to increase confidence in the establishment of categories. This comment was not directed at any of the substances in the tall oil category in particular, but appeared to be recommended across the board as a new technology to assist in defining a class of chemicals for a category. Microarray testing, which is conducted *in vitro* using gene chips, is still experimental and will require extensive validation in animal studies. Thus, this test will not provide useful information at this time and will not be undertaken.

Environmental Fate - Photodegradation

PCA stated in its Test Plan that it would not measure photodegradation. Although EPA agreed this was a "reasonable approach for the mixtures," EPA requested estimated photodegradation data for tall oil, disproportionated tall oil and wastewater acidulation, or for their major constituents. The Agency believes that many of the components of the mixtures have low water solubilities and moderate Henry's law constants so that volatilization from water may be significant. It is PCA's understanding, however, that Henry's Law pertains to the relationship between the solubility of a gas in a liquid in comparison to its partial pressure above the liquid. Tall oil is a non volatile viscous liquid composed primarily of oleic acid, linoleic acid and rosin, none of which exist in a gaseous state at ambient temperatures. Consequently, Henry's Law is not relevant to this substance; tall oil does not vaporize at ambient temperatures so that there are no vapors to photodegrade. Accordingly, PCA will not measure photodegradation of the substances in this category since their low solubility and lack of vapor pressure at ambient temperatures provide essentially no opportunity for the chemicals to enter the atmosphere.

In addition, estimating photodegradation of the major constituents of the sponsored substances is outside the scope of PCA's sponsorship under the HPV Program. Notably, however, many of the major constituents have been sponsored by SDA so that EPA should receive at least some of the data it is requesting. Consequently, estimation of photodegradation of the constituents will not be undertaken by PCA.

Environmental Fate - Transport & Distribution

EPA also recommends that PCA estimate fugacity (transport and distribution between environmental compartments) for the major components of each substance in the tall oil category. Although the Agency recognizes that "*parameter values for the individual components are not truly representative of* the mixtures in this category, EPA believes that fugacity calculations for the major components of each mixture would prove useful in understanding the environmental behavior of the mixtures."

SDA has volunteered for many of the components so that the requested data should be forthcoming. However, PCA does not believe that estimated fugacity calculations for the components would be useful for assessing the sponsored chemicals. EPA likewise acknowledged that these calculations are *not representative of the sponsored chemicals.* PCA notes that its commitments run to the mixtures themselves as a whole (not the major components) and, thus, will not undertake these calculations.

Ecotoxicity Tests

EPA agreed with the proposed acute toxicity testing of fish, daphnia and algae, but also suggested that PCA conduct a 21-day chronic daphnid reproduction test using a flow-through method with measured concentrations. In contrast, PCRM stated that fish testing of tall oil is "inappropriate" and questioned the relevance of the results from the proposed testing.

After consideration of these comments, PCA does not intend to amend its Test Plan with regard to the proposed ecotoxicity testing. The methodology for preparing the water for PCA's ecotoxicity testing of distilled tall oil is identical to that used to determine the solubility of this substance. This procedure was adopted in order to ensure that ecotoxicity testing was conducted at the limit of actual water solubility. Given the extremely low solubility of the material, EPA's recommendation for a 21-day test using a flow-through method would be impracticable from an experimental perspective. Based on the amount of water that would be required and the difficulty in performing the necessary serial analytical measurements, a flow-through test for tall oil is simply not feasible. In addition, where there is a risk of emulsions forming inherently (as there might be with this substance), flow-through testing in not possible and is not recommended pursuant to the OECD (2000) Guidance Document 23 (Aquatic Toxicity Testing of Difficult Substances and Mixtures), which EPA specifically recommends PCA should follow. Thus, chronic aquatic toxicity testing in daphnia is not appropriate for this substance.

Human Health Effects

PCA proposed to conduct a combined repeat-dose toxicity test with reproductive and developmental toxicity screens and genotoxicity testing (bacteria and mammalian cells) on tall oil to represent all members of the category. EPA reiterated its concern that test results for tall oil may not be representative of pitch and disproportionated tall oil. The Agency suggested that PCA may need to conduct acute toxicity testing on these substances to support the analogy to tall oil. As described in our category and substance rationale, disproportionated tall oil is qualitatively similar to tall oil and therefore no additional testing on this compound will be undertaken. However, because of the inability to fully characterize tall oil pitch, acute toxicity testing (OECD 425) on this compound will be undertaken in order to demonstrate its similarity to other members of this category.

Environmental Defense also recommended that PCA consider testing tall oil and tall oil pitch for estrogenic activity in a screening assay. Such testing is

not included within the HPV Program (which ED acknowledged) and, accordingly, will not be undertaken by PCA as part of its HPV sponsorship.

Amendment to the Test Plan:

Tall oil pitch (CAS # 8016-81-7), will be tested using OECD 425 (up-down procedure) to demonstrate that the results from the tall oil toxicity testing are representative of tall oil pitch and pitch salt.

The revised Table 1 below incorporates the additional acute test on tall oil pitch, as well as provides a complete picture of the testing to be performed under this Test Plan.

PCA appreciates the comments from EPA, ED and PCRM, as well as the opportunity to respond. We look forward to sharing the data generated pursuant to the Test Plan.

Respectfully submitted,

Walter L. Jones
President & COO

Table 1
Available Adequate Data and Proposed Testing On Tall Oil and Related Substances*

Chemical and CAS #	Required SIDS Endpoints										
	Partition Coef.	Water Sol.	Biodeg.	Acute Fish	Acute Daph.	Acute Algae	Acute oral	Repeat Dose	Gene muta-tion	Chrom-osomal aber-rations	Repro/ Develop
8002-26-4, Tall Oil	Test	Test	Adeq.	Test	Test	Test	Adeq.	Test	Test	Test	Test/ Test
8016-81-7, Tall Oil Pitch	Test	LM	Adeq.	C	C	C	Test	C	C	C	C
68140-16-9, Tall Oil Pitch, sodium salt	Test	Test	Test	C	C	C	C	C	C	C	C
68152-92-1, Tall Oil, dispro-portionated	Test	Test	Test	C	C	C	C	C	C	C	C
65997-01-5, Tall Oil, sodium salt	Test	Test	Test	C	C	C	C	C	C	C	C
68647-71-2, Tall Oil, potassium salt	Test	Test	Test	C	C	C	C	C	C	C	C
65997-02-6, Wastewater, tall oil soap acidulation	No test	No test	No test	C	C	C	C	C	C	C	C

Adeq. Indicates adequate existing data
Test Indicates proposed testing
No test See test plan for explanation
LM Lack of a suitable analytical method precludes testing
C Indicates category read-down from existing or proposed test data on tall oil,
*No testing will be conducted for melting point, boiling point, vapor pressure, hydrolysis, photodegradation and transport and distribution between environmental compartments, as explained in the test plan.